UCB Global Methodological Note

Pursuant to Chapter 5 of the EFPIA Code of Practice and the IPHA Code of Practice for the Pharmaceutical Industry

This note describes the global position from UCB with regards to the IPHA Code of Practice disclosure requirements.

INDEX:

Inspired by patients.
Driven by science.

1. Context

At UCB, we focus on creating value for people living with severe diseases by delivering medicines and solutions that improve their lives.

We work with stakeholders to address the unmet needs of patients and caregivers, helping them to achieve their goals and to live the lives they want.

Patients, their representatives and their caregivers, medical professionals and organisations can offer invaluable knowledge on patients' needs, behaviour and management of diseases. Engaging with such healthcare stakeholders is therefore essential for UCB and other pharmaceutical companies to improve patient care and treatment and has long been a positive driver for advancements in innovative medicine and patient value creation.

In UCB, we believe that the interest of patients and other stakeholders in the transparency of these interactions is compelling.

We are dedicated to demonstrating complete integrity and honesty in our relationships with healthcare stakeholders, including patient organisations, individual patients and their caregivers, healthcare professionals and organisations such as hospitals. Those interactions, initiated for proper, scientific reasons, unrelated to any purchases, prescriptions, or distribution of our products by those healthcare professionals or to their position, may be related to Transfers of Values (ToVs), whether in kind or in cash.

Such financial relationships should occur without potential conflicts of interest and be fully independent of the clinical decisions. Patients need to know that they can trust their doctor to recommend, prescribe and administer appropriate care and treatments based solely on clinical evidence and experience. UCB recognizes its responsibility in supporting a fair and open partnership and protecting the high standards of integrity that patients, governments and other stakeholders expect. Therefore, our interactions with healthcare stakeholders are based on standards of ethics, integrity and fair market value.

There is an expectation that such interactions between corporations and society are not only conducted with integrity but are also transparent. The pharmaceutical industry believes that it is critical to respond to society's expectations and for this reason, the European Federation of Pharmaceutical Industry and Associations (EFPIA) and the Irish Pharmaceutical Healthcare Association (IPHA) requires to its member companies to disclose the nature and scale of their interactions with healthcare stakeholders.

As an EFPIA and IPHA Member Company, UCB is dedicated to complying with the disclosure of transfer of value requirements and is ensuring that our policies continue to align with the industry standards in all the countries where we operate. On an annual basis and as from 2016, UCB is making publicly available details of ToVs made to Patient Organisations, Healthcare Professionals (HCPs) and Healthcare Organisations (HCOs) during the previous calendar year.

This note describes UCB's general methodology used to prepare the disclosure report in accordance with the EFPIA and IPHA requirements as well as our company interpretation of the above-mentioned requirements. Any variations or clarifications based on the requirements of the IPHA Code of Practice have also been included for submission with the UK country report.

We hope that this enables public scrutiny and understanding of these relationships, and therefore contribute to the trust of stakeholders and patients in the pharmaceutical industry.

2. Scope

2.1 Categories of Recipients

The following categories of recipients are included in the disclosure reports published by UCB in accordance with the EFPIA Code of Practice and IPHA Code of Practice disclosure requirements.

2.1.1. Healthcare Professionals

According to the IPHA Code of Practice, the term Healthcare Professional (HCP) means a person of any of the following classes: (i) Registered medical practitioners, (ii) Registered dentists, (iii) Registered pharmacists, (iv) Registered nurses, or any other person who, in the course of his/her professional activities, may prescribe, purchase, supply, recommend or administer a Medicinal Product and whose primary practice, principal professional address or place of incorporation is in Europe.

For the purpose of disclosure, we also consider Other Relevant Decision Makers (ORDMs) to be included under the definition of HCPs. ORDMs are those who are in a position where they could influence in any way the administration, consumption, prescription, purchase, recommendation, sale, supply or use of any medicine but are not healthcare professionals.

2.1.2. Healthcare Organisations

A HCO is defined as any legal person/entity (i) that is a healthcare, medical or scientific association or organisation (irrespective of the legal or organisational form) such as a hospital, clinic, foundation, university or other teaching institution or learned society (except for POs within the scope of Annex III) whose business address, place of incorporation or primary place of operation is in Europe or (ii) through which one or more HCPs or ORDMs provide services.

2.1.3. Patient Organisation (PO)

A PO is defined as a non-for-profit legal person/entity (including the umbrella organisation to which it belongs), mainly composed of patients and/or caregivers, that represents and/or supports the needs of patients and/or caregivers and which business address, place of incorporation or primary place of operation is in Europe.

2.1.4. Patient Organisation Representative

A PO representative is a person who is mandated to represent and express the collective views of a PO on a specific issue or disease area.

2.1.5. Patient and Caregiver

A patient is a person who is awaiting or under medical care and/or treatment; a caregiver is a person (not being an healthcare professional) who provides direct care to a patient

2.2 Categories of Transfers of Value (ToVs)

Below are the categories of transfers of value as defined by the IPHA Code of Practice relating to HCP/HCO disclosure of ToVs.

EFPIA or IPHA category	UCB activities
Donation and Grants According to the EFPIA/IPHA Code of Practice Donations and Grants collectively, mean providing funds, assets or services freely given for the purpose of supporting healthcare, scientific research or education, with no consequent obligation on the recipient to provide goods or services to the benefit of the donor in return.	This category includes the financial or in-kind donations and grants provided to HCOs by UCB to support programs that foster increased understanding of scientific, clinical, and healthcare issues that contribute to the enhancement of patient care. This type of support is not linked to any benefit in return for UCB. Examples of programs that may be considered for such funding: • Educational workshops for healthcare providers and patients; • Development of educational tools or resources to enhance physician-patient dialogue about treatment of disease; • Innovative technology platforms that enhance management of disease and aim to improve patient lives and their care • Studentship/fellowship program; • Equipment to improve patient care or funding of a research chair at a university; • Donation of services from a third party to an external organization. UCB also supports institutions that raise awareness of the needs of those with severe diseases, to further medical and scientific knowledge, and to build strong communities in several key areas of interest in which UCB operates, such as immunology and neurology. ⚠ No donations or grants are provided to individual HCPs by UCB.
Contribution to costs and events Member Companies must comply with criteria governing the selection and support of HCPs or POs' Representatives to attend Events s No payment must be offered to compensate merely for the time spent by the HCP or PO's Representative in attending Events.	This category includes the costs associated with the sponsorship of events fostering medical and scientific knowledge. In return, UCB receives benefits such as opportunities to promote our products, our company, and/or specific disease awareness activities. Benefits covered under the terms of a sponsorship agreement can include: • Rental of booth or exhibit space at an event; • Advertisement space (paper, electronic or another format); • Satellite symposium at a scientific congress; • If part of a package, drinks or meals provided by the organisers; • Corporate membership to an association. • Individual sponsorships of HCPs to attend scientific/educational events. These may cover travel, accommodation and potential congress registration fees for the HCP.

	➢ In case a given HCP could not participate to the congress or meeting for any reason, and therefore could not derive any benefit from it, any costs already incurred in case of such a 'no-show' are not reported. ➢ The logistical and management fees charged by commercial agencies or travel agencies in the context of an event are not part of the disclosure. ➢ Reporting of Indirect ToVs to HCOs made through Professional Conference Organisers (PCOs). When a payment is made to a PCO and the HCO or HCP is known, this Indirect ToV is reported in the name of the benefitting HCO/HCP, if not already included in the direct ToVs to the HCO.
Fee for service and consultancy ToVs resulting from or related to contracts between Member Companies and HCOs under which such HCOs provide any type of services to a Member Company or any other type of funding not covered in the previous categories. Fees, on the one hand, and on the other hand ToVs relating to expenses agreed in the written agreement covering the activity will be disclosed as two separate amounts.	UCB engages HCPs or HCOs in exchange of a monetary compensation and/or a benefit in kind for purposes such as: • Consulting or advising services (e.g. provision of scientific expertise on specific topics during an advisory board); • Speaker activities (e.g. scientific symposia or other medical/educational meetings, or similar activities at congresses); • Medical writing (e.g. editorial support for scientific publications). ➢ Service Agreements related ToVs may include fees or honoraria, but also expenses incurred in the course of the provision of the services, such as travel and accommodation. ➢ In case of cancellation, UCB may compensate any services already incurred in the context of a contractual arrangement, such as preparation time for speaker activities and those compensations are included in UCB's reports.
Research and Development ToVs to HCPs or HCOs related to the planning or conduct of (i) non-clinical studies (as defined in OECD Principles on Good Laboratory Practice); (ii) clinical trials (as defined in Regulation 536/2014); or (iii) NIS that are prospective in nature and that involve the collection of patient data from or on behalf of individual, or groups of, HCPs specifically for the study.	This section covers all Research and Development activities undertaken to discover and develop new therapies to treat patients suffering from severe diseases, such as but not limited to, clinical trials (UCB-conducted or independently conducted) designed to verify or study the clinical effects of one or more medicinal product(s) and identify any adverse reactions in order to ascertain its (their) safety and/or efficacy, or partnerships with both academia and leading drug discovery foundations. Affiliates that follow the reporting template as recommended by EFPIA/IPHA disclose TOVs relating to Research and Development in an aggregate format. ⚠ This excludes fees provided in the context of a retrospective Non-Interventional Study (NIS). Such fees and their related expenses are not considered as part of research work as defined above and will therefore be reported under the section *"Fees for Service and Consultancy"* of the Disclosure Report. Similarly, other R&D consultancy services that are not in the scope of a clinical trial agreement are reported under *"Fees for Service and Consultancy".*

3. Patient Organisation disclosure

According to EFPIA and IPHA Code of Practice, UCB will disclose as a separate report any financial and/or significant indirect/non-financial transaction with patient organisations that UCB supports or with whom UCB has engaged to provide contracted services.

The disclosure report includes a description of the nature of the support or services.

4. Form of disclosure

a. Excluded from disclosure

In the UCB Disclosure Report the following are not included:

- ToVs that are solely related to over-the-counter medicines, items of medical utility, meals and drinks, samples or are part of ordinary course purchases and sales of medication by and between a company and an HCP or in accordance with IPHA general guidance.
- In case an HCP or patient/patient representative invited by UCB needs the support from an accompanying caregiver, ToVs related to that caregiver, such as travel costs, are not included in the Disclosure Report.
- With a view to disclosing data as accurately as possible, ToVs that seemed to be related to technical issues have been filtered out of all Reports.
- ToVs related to commercial agreements with an HCO (e.g. rebate or commercial discount, rental of advertising space with a non-HCO) are not in scope of the disclosure requirements.
- Funding of Continuing Medical Education (CME) events organized by commercial providers are not considered as part of the scope, and therefore not part of the Disclosure Report, on the condition that UCB is not involved in the organisation of the event nor in the selection of participants.
- TOVs related to individual patients are not included in the Disclosure Report.

b. Over-disclosure

In relation to working with HCPs and HCOs, since the introduction of the EFPIA and IPHA Disclosure Codes, EFPIA and IPHA have worked to encourage Member Companies to always look to disclose and to encourage HCPs to agree to individual disclosure. Member Companies will not be criticized for over-disclosure (EFPIA Code of Practice-Introduction section pg.12).

With a view of achieving full transparency, UCB decided to include ToVs relating to all marketed products, including over-the-counter products as well as molecules or compounds in development, whenever the purpose and nature is covered by the EFPIA and IPHA Disclosure requirements (e.g., fees for service and consultancy).

c. Reporting format and Period

UCB is using the reporting template provided by the EFPIA or the local industry associations, or defined per law whenever applicable.

The Disclosure Reports will be available annually at the end of the second quarter of the year subsequent to the reporting period. The reporting period covers all ToVs that occurred from 1st January to 31st December of the previous year, including the ones related to events attended or services provided before the reported year.

Reports will remain available online for a period of three years.

d. Platform of disclosure

The Disclosure Reports are published on UCB's Corporate website, which in turn links into the IPHA Central Report.

e. Language

The language of disclosure is by default the language of the country for which it is published.

f. VAT

Value Added Tax (VAT) is included by default in the disclosed ToVs, The Euro is used for all disclosed amounts. Non-local currencies are converted, based on the rate at payment date for direct payments, or date of the event for indirect payments.

5. UCB Specifics

a. Consent Management

UCB is dedicated to disclose ToVs under the names of individual recipients. At the same time, UCB is committed to complying with applicable data protection laws, which may impose certain limitations on the ability to make disclosures on an individual basis. UCB makes sure to obtain consent of individual healthcare stakeholders prior to the actual disclosure. UCB preferred approach for consent collection is on a contract by contract basis.

UCB recognizes the right of an individual to decline or revoke consent to the publication of individual ToVs. As a general rule, UCB has decided not to consider disclosure consent as a prerequisite for collaboration. However, UCB will not accept partial consent when the refusal or revocation only concerns a specific transfer of value or a specific time period.

When individual disclosure is declined or revoked, disclosure will happen at an aggregate level, meaning a total amount per categories as defined above for the number of anonymous recipients. Accepting revocation of consent for one or more recipients implies that Disclosure Reports are subject to change, even after publication.

b. ‘‘Follow the money’’

UCB adheres to the general principle of “follow the money”: whenever possible, the ultimate beneficiary of a ToV is the one that shall be reported. The Disclosure Report includes all ToVs to any covered recipient (as defined above) regardless of whether it has been handled by UCB directly or through a third party acting on behalf of UCB (indirect payment). If the names of the individual beneficiaries as well as the benefit/actual amount are known to UCB, all the related ToVs made on behalf of UCB will be reported under the name of the ultimate beneficiary (including non-blinded market research for instance).
Payments made to a legal entity such as an HCO are reported under the name of that legal entity.
Each ToV is only reported once, in the recipients’ country of principal practice, taking as a reference the physical address where the individual has is home address or primary professional practice or where the HCO/PO is registered, regardless of whether the ToV occurs within or outside of Europe.